OCT 1 3 2000

K002909

Special 510(k) Summary

Contact Person:	Dr. Bruce L. Gibbins, Chairman & CTO
Contact Information:	AcryMed Incorporated 12232 SW Garden Place Portland, OR 97223 Phone: (503) 624-9830 Fax: (503) 639-0846
Date of preparation:	September 13, 2000
Device Name (proprietary):	AcryDerm Silver Anti-microbial Strands
Common Name:	Moist wound dressing
Classification Name:	Hydrophilic wound dressing
Classification:	Unclassified; as recommended by the General and Plastic Surgery Devices Panel 79

Legally marketed device(s) for substantial equivalence comparison:
AcryDerm Silver Antimicrobial Dressing, (AcryMed, Inc.)
AcryNoodles Absorbent Wound Dressing (AcryDerm, Inc.)

Description of Device: AcryDerm Silver Antimicrobial Strands is an absorbent hydrophilic polyacrylate based wound dressing that contains antimicrobial silver. The new product is made from the same base matrix material that is used in the production of its predicate, AcryDerm Silver Antimicrobial Dressing (K991818). The new product is a stranded version of the silver containing sheet format. This format is identical to our previously cleared AcryNoodles Absorbent Dressing (K962851) excepting that it is composed of substrate identical to that used in AcryDerm Silver Antimicrobial Dressing that is currently manufactured for market.

Indications and Intended Use of the Device: AcryDerm Silver Antimicrobial Strands is an effective barrier to bacterial penetration. The barrier function of the dressing may help reduce infection in partial and full thickness wounds including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, abrasions and lacerations, donor sites and surgical wounds. AcryDerm Silver may be used over debrided and grafted partial thickness wounds.

Technological Characteristics: AcryDerm Silver Antimicrobial Strands is composed of the same material used in the production of the predicate, AcryDerm Silver Antimicrobial Dressing. The device contains a form of silver that is converted to ionic silver upon contact with aqueous moisture such as that found in exudate.

Performance Standards. There are performance standards that apply to AcryDerm Silver Anti-microbial Strands.

Manufacturing: AcryDerm Silver Antimicrobial Strands will be manufactured according to the product specifications and under good manufacturing practices that ensure the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2000

Bruce L. Gibbins, Ph.D.
Chairman and Chief Technical Officer
AcryMed, Inc.
12232 SW Garden Place
Portland, Oregon 97223

Re: K002909
Trade Name: AcryDerm Silver Antimicrobial Strands
Regulatory Class: Unclassified
Product Code: KMF
Dated: September 12, 2000
Received: September 18, 2000

Dear Dr. Gibbins :

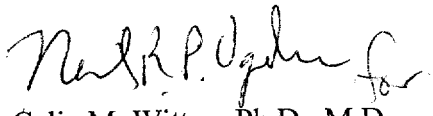
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (~~for the indications for~~ use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, ~~or to devices that~~ have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002909

510(k) NUMBER (IF KNOWN): K002909

DEVICE NAME: **AcryDerm Silver Antimicrobial Strands**

INDICATIONS FOR USE:

AcryDerm Silver Antimicrobial Strands is an effective barrier to bacterial penetration. The barrier function of the dressing may help reduce infection in partial and full thickness wounds including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, abrasions and lacerations, donor sites and surgical wounds. AcryDerm Silver may be used over debrided and grafted partial thickness wounds.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use X
(Per 21 CFR 801.109)

OR Over-The-Counter-Use
(Optional Format 1)

Mark N. Milhem
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002909

9-25-00